

Applicants: Beth Borowsky, et al.  
Serial No.: 10/018,192  
Filed: June 24, 2002  
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**REMARKS**

Claims 166-173 were pending in the subject application. By this Amendment, applicants have amended claims 166-173, without prejudice. Accordingly, upon entry of this Amendment, claims 166-173, as amended, will be pending and under examination.

Applicants maintain that the amendments to claims 166-173 raise no issue of new matter. Applicants have made amendments to claims 166-173 to correct obvious grammatical or typographical errors. Applicants have also made amendments to claims 166-173 to delete the word "pharmaceutical" from the phrase "pharmaceutical composition" or to delete the phrase "pharmaceutically acceptable amount". Applicants have also made amendments to the specification to provide a descriptive title of the invention and to include the proper sequence identifiers in the description of Figures 7, 8, 11 and 12.

Support for the amendments to the description of Figures 7A-7B on page 26 may be found inter alia in the sequence listing of the specification as originally filed in SEQ ID NO:1, at nucleotide positions 460 to 759; and in SED ID NO:5.

Support for the amendments to the description of Figure 8 on page 26 may be found inter alia in the sequence listing of the specification as originally filed in SEQ ID NO:2, at amino acid positions 151 to 250; and in SED ID NO:6.

Support for the amendments to the description of Figures 11A-11D on page 27 may be found inter alia in the sequence listing of the specification as originally filed in SEQ ID NO:1, at nucleotide positions 10 to 1446; and in SED ID NO:7, at nucleotide positions 25 to 1449.

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Support for the amendments to the description of Figures 12A-12B on page 27 may be found inter alia in the sequence listing of the specification as originally filed in SEQ ID NO:2; and in SED ID NO:8.

Accordingly, applicants respectfully request that this amendment be entered.

### **Formalities**

#### 1. Priority

On page 2 of the April 19, 2004 Office Action, the Examiner requested that the status of the prior applications be included in the first sentence of the specification.

Applicants have hereinabove, on page 2 of this paper, amended the specification to state the current status of the priority documents.

#### 2. Information Disclosure Statement

On page 2 of the April 19, 2004 Office Action, the Examiner alleged that a May 14, 2002 Information Disclosure Statement is not present in the file.

Applicants attach hereto as **Exhibit 1** a copy of the Information Disclosure Statement filed May 14, 2002 including Form PTO-1449 in which the following references were made of record:

1. U.S. Patent No. 6,008,338, issued December 28, 1999;  
and
2. Provencio, I., et al., "Melanopsin: An opsin in Melanophores, Brain and Eye, *Proc. Ntl. Acad. Sci.*, January 1998, 95: 340-345.

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Accordingly, applicants respectfully request that the Examiner make the prior art of record.

### Objections to the Specification

#### 1. Sequence Identifiers

On page 3 of the April 19, 2004 Office Action, the Examiner alleged that sequences are disclosed in Figures 7, 8, 11 and 12 without the required reference to the sequence identifiers (SEQ ID NOS:). The Examiner then stated that applicants are required to amend the specification and claims to comply with 37 C.F.R. 1.182(d).

Applicants have hereinabove, on pages 2-3 of this paper, amended the specification to include sequence identifiers in the description of Figures 7, 8, 11 and 12. Applicants maintain that proper sequence identifiers (or reference to the Figures) are present in the specification and claims wherever reference is made to that sequence, therefore the instant application complies with 37 C.F.R. 1.182(d).

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this objection to the specification.

#### 2. Title of the Invention

On page 3 of the April 19, 2004 Office Action, the Examiner alleged that the title of the invention is not descriptive, and required a new title that is clearly indicative of the claimed invention.

Applicants have hereinabove amended the title of the invention to recite "Compositions Comprising SNORF36 Receptor Compounds".

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Accordingly, applicants maintain that the new title clearly describes what is currently being claimed and respectfully request that this objection to the specification be withdrawn.

#### **Objections to the Drawings**

On page 3 of the April 19, 2004 Office Action, the Examiner alleged that Figure 7A (page 14) of the Drawings is missing. Applicants attach hereto as **Exhibit 2** a copy of Figure 7A of the Drawings filed with the U.S. Patent Office on June 24, 2002.

#### **Objections to the Claims**

On page 4 of the April 19, 2004 Office Action, the Examiner objected to claims 169 and 173 because of alleged grammatical and typographical errors.

In response, applicants have amended claims 169 and 173 to correct the grammatical and typographical errors.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw these objections.

#### **Obviousness-type Double Patenting**

On page 4 of the April 19, 2004 Office Action, the Examiner rejected claims 166-173 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-36 of U.S. Patent No. 6,413,731. The Examiner acknowledged that the conflicting claims are not identical, however the Examiner alleged that they are not patentably distinct from each other.

The Examiner stated that the claims in Patent No. 6,413,731 are drawn to a method of screening for compounds that bind to, activate or inhibit the receptor of SNORF36a receptor (SEQ ID

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NO:2), and the claims of the instant application are drawn to a method of screening for compounds that bind to, activate or inhibit the receptor of SNORF36a receptor (SEQ ID NO:2) and admixing a pharmaceutically acceptable carrier. The Examiner then alleged that it would be *prima facie* obvious to one of ordinary skill in the art to admix a pharmaceutically acceptable carrier to a compound that was found to bind to, activate or inhibit the receptor of SNORF36a receptor, in order to test the compound in an animal model of a disease or disorder, in order to determine the effects of the compound on the animal.

Applicants will consider filing a terminal disclaimer in compliance with 37 C.F.R. 1.321(c) showing that the conflicting patent and instant application are commonly owned, upon the Examiner's indication of allowable claims.

**Rejection under 35 USC §112**

On page 5 of the April 19, 2004 Office Action, the Examiner rejected claims 166-173 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner alleged that claims 166-173 encompass a "pharmaceutical use" for the compositions. The Examiner then alleged that for the claims to be enabled, the specification must teach how to use the composition in at least one pharmaceutical use without undue experimentation.

The Examiner further alleged that the specification does not provide adequate guidance as to how the identified compounds can be used to treat or diagnose any disorders. The Examiner alleged

that it is not predictable from the *in vitro* experiments of the instant specification or from the teachings of the prior art that antagonists or agonists of SNORF36 could be used to treat the diseases or disorders asserted in the specification.

The Examiner then acknowledged that the specification enables a method of preparing "a composition" comprising admixing a pharmaceutically acceptable carrier with a compound that binds to, activates or inhibits the receptor of SEQ ID NO:2 of the instant application. The Examiner acknowledged that deleting the word "pharmaceutical" in the term "pharmaceutical composition" or deleting the term "pharmaceutically acceptable amount" in the claims would obviate the rejection.

In response, in an attempt to advance prosecution but without conceding either the need for amendment or the correctness of the Examiner's position, applicants have amended claims 166-173 to delete the word "pharmaceutical" from the term "pharmaceutical composition" or the term "pharmaceutically acceptable amount".

Accordingly, applicants maintain that claims 166-173 comply with the requirements of 35 U.S.C. §112, first paragraph and respectfully request that the Examiner reconsider and withdraw the rejection.

#### **Rejection under 35 USC §112**

On page 8 of the April 19, 2004 Office Action, the Examiner alleged that applicants referral to the deposit of plasmid pcDNA3.1-hSNORF36a-f on page 31 of the specification is not sufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1,809 have been met. The Examiner alleged that if the deposits were made under the provisions of the Budapest Treaty, then the filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that

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the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon access to the deposits will be irrevocably removed upon the grant of a patent on the application and that if the deposit will be replaced if viable samples cannot be dispensed by the depository is required.

In response, applicants' undersigned attorney states herewith that in accordance with 37 C.F.R. §1.808(a)(2) all restrictions imposed by the depositor on the availability to the public of the deposited materials will be irrevocably removed upon the granting of a patent from the subject application. Applicants attach hereto as **Exhibit 3** a copy of the ATCC Deposit Receipt for plasmid pcDNA3.1-hSNORF36a-f (ATCC Accession No. 203977) indicating that the deposit was made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure on April 28, 1999.

Applicants also note that the date of the deposit, the complete name and address of the depository, and the accession number of the deposited plasmid can be found in the specification as originally filed on page 31, lines 8-15.

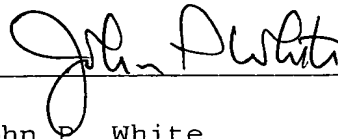
Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided.

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No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

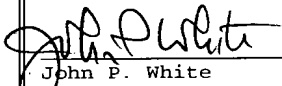
Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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 6/22/04  
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# ATCC



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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF  
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

**INTERNATIONAL FORM**

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3  
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

**To: (Name and Address of Depositor or Attorney)**

Cooper & Dunham LLP  
Attn: John P. White, Esq.  
1185 Avenue of the Americas  
New York, NY 10036

**Deposited on Behalf of:** Synaptic Pharmaceutical Corporation (Ref. Docket 59138)

**Identification Reference by Depositor:**

**Patent Deposit Designation**

Plasmid pcDNA3.1-hSNORF36a-f

203977

The deposit was accompanied by: \_\_\_ a scientific description \_\_\_ a proposed taxonomic description indicated above.

The deposit was received April 28, 1999 by this International Depository Authority and has been accepted.

**AT YOUR REQUEST:** X We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested May 5, 1999. On that date, the culture was viable..

**International Depository Authority:** American Type Culture Collection, Manassas, VA 20110-2209 USA.

**Signature of person having authority to represent ATCC:**

Barbara M. Hailey  
Barbara M. Hailey, Administrator, Patent Depository

**Date:** June 16, 1999